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March 31, 1999

4/5/99

Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR § 101.93, that Rexall Sundown, Inc. located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown Herbals brand name bearing the following statement(s) on the label and/or in the labeling:

Ginkgo Biloba: For mental alertness. The Ginkgo Biloba tree has been known for its health-promoting effects for thousands of years. Ginkgo Biloba stimulates healthy brain function, memory and mental alertness by increasing blood circulation to the brain. Ginkgo Biloba also works as an antioxidant to protect against cellular damage and enhance health. As a complement to Sundown's Standardized Ginkgo Biloba, take this product with Sundown's Lecithin and CoQ-10 products. Lecithin, a necessary constituent of every living cell, keeps cell membranes elastic. CoQ-10 works as a powerful antioxidant to help protect cellular membranes from free radical damage.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

Deborah Shur Trinker
Vice President of Regulatory Affairs
and Assistant General Counsel

Enclosure

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